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Amendment
Attorney Docket No. S63.2H-12013-US01

Remarks

This Amendment is in response to the Office Action dated **January 24, 2005**, wherein claim 2 was objected to; claims 51, 53, 59, 60, 63 and 65 were rejected under the judicially created doctrine of double patenting; claims 1-7, 10, 11, 13, 18, 42-48, 50, 51, 53, 56, 59, 60, 63, 65-68, and 70 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,165,195 to Wilson et al (hereinafter: Wilson); claims 1-7, 10-12, 15, 18, 42, 45, 48, 50, 51, 53-55, 58-60, 63, 65, and 66 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,086,611 to Duffy et al (hereinafter: Duffy) or in the alternative under 35 U.S.C. §103(a) as being obvious over Duffy in view of Wilson; and claims 14 and 57 were rejected under 35 U.S.C. §103(a) as being obvious over Duffy and Wilson in further view of U.S. 5,851,464 to Davila et al (hereinafter: Davila).

The following comments are presented in the same order and with paragraph headings corresponding to the Office Action.

Applicants respectfully request favorable consideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Examiner Interview

It is noted that the Applicants of the present Application recently transferred responsibility for the further prosecution of the Application to the undersigned attorney. Applicants previous representative, Michelle Franks, conducted an interview with Examiner Prebille on April 21, 2005. During the interview, distinctions between the claimed invention and the Wilson, et al. and Duffy, et al. prior art as applied by the examiner were discussed. The examiner indicated that he needed to further consider the arguments.

Claim Objection

Claim 2 has been objected to because the language of this claim repeats language found in base claim 1. The Examiner has stated that correction is required.

Claim 2 has been cancelled without prejudice or disclaimer. Withdrawal of the rejection is required.

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Double Patenting

Claims 51, 53, 59, 60, 63 and 65 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8, 9, 12, 15 and 21 of U.S. Patent No. 6,692,483.

Included in this filing is a Terminal Disclaimer to Obviate a Double Patenting Rejection Over a Prior Art Patent including the associated fee under 37 C.F.R. 120(d). Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC §102

Wilson '195

Claims 1-7, 10, 11, 13, 18, 42-48, 50, 51, 53, 56, 59, 60, 63, 65-68 and 70 were rejected under 35 U.S.C. 102(e) as being anticipated by Wilson. Claims 1 and 50 are independent.

In the Office Action it is asserted that Wilson has a side member 55A, which has an unattached end that springs away from catheter 35 to redirect the guidewire. According to the Office Action, "[S]ince all the elements of the Wilson device can be made radiopaque, the claim language requiring radiopaque markers in the catheter' and side member is fully met." (Id.)

Wilson discloses that the distal end 55B of the guide wire lumen will spring outwardly *which facilitates advancing guide wire distal end 41B into the side branch vessel*. (Id.) The function of this angled guide wire lumen is to *advance the guide wire into the branch vessel* (See Col. 16, lines 58-62.) Wilson further discloses that to properly align both the proximal angled stent 10 and main vessel stent 20 in the side branch vessel 5 and main vessel 6, positioning guide wire lumen 39A, on side branch catheter, and guide wire lumen 55A, on main vessel catheter 50, can be radiopaque or have a radiopaque marker associated therewith so that they are visible under fluoroscopy. (Col. 17, line 64— Col. 18, line 15.)

From the above, it is clear that although Wilson recognizes the desire for visibility under fluoroscopy, it does so in only a basic and generic fashion. The disclosure that the

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guidewire lumen springs out to direct the guidewire into the branch and any part can be made radiopaque does not result in the invention as claimed. Wilson simply fails to disclose uniquely positioning markers in a juxtaposed arrangement in a first configuration and separated in a second configuration at the side branch as claimed in claims 1 and 50. The fact that someone "could have" contemplated the claimed invention based upon the generic teaching of markers for positioning and a springing guidewire lumen for wire advancement is impossible without relying on hindsight and using the Applicants' claim as a roadmap.

To further clarify this feature, Applicants have amended claims 1 and 50 to call for an indicator to indicate that the distal end of the side member is advancing into a branch vessel, the indicator comprising at least one radiopaque marker positioned on the side member, wherein the at least one radiopaque marker positioned on the catheter and the at least one radiopaque marker positioned on the side member are juxtaposed in a first configuration and separated in a second configuration to indicate that the distal end of the side member is advancing into the branch vessel. (Applicants' spec, at p. 14.) Wilson fails to disclose the claimed invention. At least for the reasons discussed above with respect to claims 1 and 50, dependent claims 3-7, 10, 11, 13, 18, 42-48, 51, 53, 56, 59, 60, 63, 65-68 and 70 also are patentable. It is respectfully requested that the rejection under 102(e) be withdrawn.

Duffy alone or in combination with Wilson

Claims 1-7, 10, 11, 12, 15, 18, 42, 45, 48, 50, 51, 53-55, 58-60, 63, 65 and 66 were rejected under 35 U.S.C. 102(e) as being anticipated by to Duffy, or in the alternative, under 35 U.S.C. 103(a) as being obvious over Duffy, in view of Wilson. This rejection is respectfully traversed.

In the office action the examiner takes the position that the radiopaque markers as claimed are connectors 9 and references the abstract and Figures 1-4. (Office Action at p. 4.) In particular the Examiner takes the position that Figure 2 shows markers that can be considered adjacent in a straight configuration and the movement of the side branch is at the deployment site. (*Id.*)

In Duffy the stent is of a modular construction. The modules are formed from a wire that is wrapped with its free ends connected to a spine (connector 9) and is formed into a

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bifurcated stent having a trunk with two legs. The spine (connector 9) defines a substantially greater mass than the individual modules such that the spine can be readily observed under x-ray or fluoroscopy. Duffy, however, fails to disclose an indicator as claimed to indicate that the distal end of the side member is advancing into the branch vessel to align the side hole of the stent with the branch vessel. In contrast, Duffy discloses a bifurcated pant stent as shown in Figure 1A and does not address alignment of a stent side hole as claimed.

Furthermore, there is no motivation to combine Duffy and Wilson. Duffy is directed a stent having a trunk with 2 legs and is modular construction, whereas Wilson is directed to a stent with side hole where guidewire sheath is used to direct guidewire into branch.

Even if combined, however, the combination merely discloses the generic concept of markers for visibility in stent delivery systems and does not disclose or suggest the claimed catheter, side member and stent with a side hole as claimed. More specifically, there is nothing in the cited references which teaches or suggests a system wherein an indicator is provided to indicate that the distal end of the side member is advancing into a branch vessel, the indicator comprising at least one radiopaque marker positioned on the side member, wherein the at least one radiopaque marker positioned on the catheter and the at least one radiopaque marker positioned on the side member are juxtaposed in a first configuration and separated in a second configuration to indicate that the distal end of the side member is advancing into the branch vessel.

Duffy alone or on combination with Wilson fails to disclose or suggest the invention as claimed in at least claims 1 and 50. At least for the reasons discussed above with respect to claims 1 and 50, dependent claims 3-7, 10, 11, 12, 15, 18, 42, 45, 48, 51, 53-55, 58-60, 63, 65 and 66 also are patentable. Withdrawal of the rejection is requested.

Additional Dependent Claims

Claims 16, 17, 19, 61, 64 and 69 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy. Claims 14 and 57 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy and Wilson, as applied to claims 1-7, 10, 11, 12, 15, 18, 42, 45, 48, 50, 51, 53-55, 58-60, 63, 65 and 66, and further in view of Davila.

At least for the reasons discussed above with respect to independent claims 1 and

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50, dependent claims 16, 17, 19, 61, 64 and 69 are patentable. Withdrawal of the rejection is respectfully requested.

Allowable Subject Matter

Claims 8 and 52 have been objected to as containing allowable subject matter but depend from a rejected base claim. Claims 8 and 52 have been rewritten in independent form as claims 72 and 73. It is respectfully submitted that claims 72 and 73 are now in condition for allowance.

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Conclusion

Upon entry of this amendment, claims 1, 4-8, 10-19, 42-48, 50-70, and 72-73 are now pending in this application. Of these claims, 1, 50, 72 and 73 are independent. By this amendment, claim 2 has been cancelled, claims 72-73 have been added and claims 1, 3-6, 16 and 50 have been amended. No new matter has been added by this amendment.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: 

By: 

James M. Urzedowski
Registration No.: 48596

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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